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09/913,763	12/21/2001	John Robert Tagg	512585-2001	5286

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Frommer Lawrence & Haug  
745 Fifth Avenue  
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EXAMINER

MELLER, MICHAEL V

ART UNIT PAPER NUMBER

1654

DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Advisory Action

Application No.

09/913,763

Applicant(s)

TAGG ET AL.

Examiner

Michael V. Meller

Art Unit

1654

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 08 December 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

## PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
 ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 08 December 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.  
 2. ☒ The proposed amendment(s) will not be entered because:  
 (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ they raise the issue of new matter (see Note below);  
 (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
 4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 5. ☒ The a) ☒ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.  
 6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.  
 7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: none

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 1, 2, 4-23 & 27-40

Claim(s) withdrawn from consideration: 24-26, 41-46

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.  
 9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_  
 10. ☐ Other: \_\_\_\_\_

Michael V. Meller  
 Primary Examiner  
 Art Unit: 1654

Continuation of 2. NOTE: the addition of "bactericidal" in claims 1, 4, the deletion of part b) in claim 1, the deletion of an organism which can express a protein as claimed in any one of claims 1-6, "a transgenic microorganism", the language deleted from claim 27 part c), the language added to claim 32 all raise new issues because they were not presented before final. They require further consideration. .

Continuation of 5, does NOT place the application in condition for allowance because: of the reasons of record. The enablement rejection is maintained. While a certain amount of routine experimentation is permitted, applicant's claim to a protein with a sequence differing by 1-3 amino acids from the sequence set forth in SEQ ID NO:3 encompasses a vast number of embodiments. Absent some guidance in the specification as to which of the amino acids can be substituted, deleted, or inserted so as to retain the claimed bacteriocidal activity, it would require undue experimentation by one of skill in the art to be able to practice the invention commensurate in scope with the claim. The written rejection is also maintained. A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli Lilly & Co., 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In Regents of the University of California v. Eli Lilly (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states "An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention". In this case, applicant has failed to describe any structure which is common to the members of the genus and which is associated with bacteriocidal activity. Therefore, one of skill in the art would not recognize from the disclosure that the applicant was in possession of the claimed genus. While the declaration filed 10/6/03 is noted, it still is not deemed to be routine experimentation to delete, insert or substitute 1-3 amino acids in a protein that is only 25 amino acids. Every single change is affecting one to three amino acids which is 4 % of the total protein per amino acid. Thus, the claims read on changing 4-12 % of the entire amino acid which is not trivial. Maybe on a protein which is 400 amino acids or higher this is trivial, but on a protein which is only 25 amino acids total it is major and there is simply not enough guidance in the specification to show that applicant was in possession of such changes to the protein or that one would know how to make such changes in such a small protein. It is not known how 1-3 changes in the amino acids will affect the properties of the protein, if the protein will still exhibit its properties.

PTOL-303 continued.

The Caufield reference does teach a protein from a different microorganism than applicants but the claims are not limited to that particular microorganism. The Caufield reference does differ by 4 amino acids but that is only a one amino acid difference from what the claims allow. One amino acid difference is within the skill of the artisan as opposed to 3 amino acid difference. Ross, Tagg, Sanders, Matsushiro and Kawai all teach the same microorganism as that claimed thus the protein from it must be the same. It is inherent to that microorganism that the protein is the same as applicants, especially within one-three amino acids insertions or deletions..